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| EXAMINER |
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TOLIN, MICHAEL A

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) |
|------------------------------|------------------------|---------------------|
| | 10/733,258 | SOLDANI, GIORGIO |
| Examiner | Art Unit | |
| | Michael A. Tolin | 1791 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 24 September 2007.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,2,5,7,8,10-23 and 25-27 is/are pending in the application.
4a) Of the above claim(s) 16-21 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1,2,5,7,8,10-15,22,23 and 25-27 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 12 December 2003 is/are: a) accepted or b) objected to by the Examiner.

 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date. _____
3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 5) Notice of Informal Patent Application
6) Other: _____

DETAILED ACTION

Allowable Subject Matter

1. The indicated allowability of claim 25 is withdrawn in view of the newly discovered reference(s) to Thorn et al. (US 4857367). Rejections based on the newly cited reference(s) follow.

Claim Objections

2. Claims 11 and 22 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claims 11 and 22 are identical in scope and language to their respective parent claims. These claims copy language from parent claim 25. Accordingly, they fail to further limit their respective parent claims.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 2, 5, 7, 8, 10-15, 22, and 25-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 25, there is no antecedent basis for "the nozzles" in line 16.

Regarding claim 5, there is no antecedent basis for "the nozzles" in parent claim 25.

Regarding claim 7, it is unclear if the claimed apparatus positively requires the wire or if the claimed apparatus only requires the capability of operating with the claimed wire. The examiner suggests amending the claim to clearly indicate that the wire is positively a part of the apparatus, or alternatively to clearly indicate that the apparatus is capable of using a wire to support a stent.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Soldani (US 5229045) in view of Pacetti (US 7175874 B1), and further in view of Hays (US 5711483) or Sobierski (US 3238059).

Soldani teaches an apparatus for making tubular porous membranes for medical use, the apparatus comprising two spray guns having nozzles and a cylindrical mandrel which can slide and rotate relative to the spray guns via rotation of the mandrel and bidirectional movement of a carriage to which the nozzles are attached. One nozzle sprays a polymer/solvent mixture while the other nozzle sprays a non-solvent mixture (Abstract; column 2, lines 24-30; column 3, lines 1-35; column 4, lines 1-25; column 6, lines 12-29). Soldani differs from the claims in that:

- i. Soldani does not recite the claimed first and second mixer means.
- ii. Soldani does not teach the claimed pumps and their position between respective mixers and nozzles.

i. Pacetti teaches an apparatus for applying coatings for a medical device. The apparatus comprises reserves, mixing means, a sprayer, and a control unit to alter the ratio of the components (Figure 1; Abstract; columns 2 and 3; column 4, lines 1-26). Pacetti teaches this arrangement allows modification of the coating as it is applied in order to tailor coatings for different applications and provide strong bonding between layers (column 1, lines 45-67; column 2, lines 1-17). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide each spray gun of Soldani with reserves, mixing means, and a central control unit because one of ordinary skill in the art would have been motivated to achieve the above noted benefits in accordance with the teachings of Pacetti.

ii. Pacetti teaches various mixers are suitable (column 4, lines 11-19). Pacetti further teaches that the solutions are moved from a mixer to a nozzle (column 3, lines

44-45). It appears that this movement occurs from the action of compressed air (column 3, lines 27-43). However, no criticality is placed on the particular means for moving fluid, and pumps are well known for providing such movement. As to the placement of the pumps, it is also well known to place a pump between a fluid source and a sprayer. For example, see Hays (Figure 1; column 1, lines 24-30) or Stobierski (Figure; column 2, lines 43-54). It would have been obvious to one of ordinary skill in the art to provide the claimed pumps in the claimed positions because one of ordinary skill in the art would have been motivated to provide the fluid movement taught by Pacetti using any well known suitable means such as pumps and one of ordinary skill in the art would have been motivated to place such pumps in any well known and suitable position such as the claimed position, as evidenced by Hays or Stobierski.

7. Claims 2, 5, 7, 8, 10-12, 22, 23, and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soldani in view of Pacetti, and further in view of Hays or Sobierski as applied to claim 1 above, and further in view of Thorn et al. (US 4857367).

While Soldani teaches the desirability of a fume hood (column 6, lines 28-29), Soldani does not recite the claimed extractor hood positioned in front of the nozzles or the claimed second carriage supporting the extractor hood which can slide in the claimed direction. It is generally known to provide a moving sprayer and extractor hood which remains in front of the sprayer in order to suitably collect excess sprayed material, as evidenced by Thorn (Abstract; Figures 1-4; column 3, lines 56-68; column 4, lines 1-2). It is further known to provide a part with desired linear movement using a

carriage assembly, as evidenced by Soldani's carriage assembly for the nozzles. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the claimed extractor hood because one of ordinary skill in the art would have been motivated to provide collection of excess sprayed material by any known and suitable means, such as that of Thorn. Further, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide the desired movement of the extractor hood using any known and suitable means, such as the claimed second carriage assembly because one of ordinary skill in the art would have been motivated to maintain the extractor hood in front of the nozzles in accordance with the teachings of Thorn by any known and suitable means such as a carriage assembly in accordance with the teachings of Soldani. The claimed parallel direction is the expected manner in which the extractor hood should be capable of moving so that it will maintain its position in front of the nozzles. Although Thorn mounts the nozzles and extractor hood to a common carriage, choosing between known means for moving equipment involves no more than routine design choice well within the purview of one having ordinary skill in the art. Only the expected result of maintaining the extractor hood in front of the nozzles has been achieved.

Regarding claim 5, Soldani teaches the claimed source of pressurized gas (column 6, lines 15-18).

Regarding claim 7, the claimed stent is "material worked on" rather than a positive limitation of the claimed apparatus. Accordingly, only the capability of using a stent is required to satisfy claim 7. The thin rotating mandrel of Soldani satisfies the

claimed wire which is capable of supporting a stent, thus satisfying claim 7.

Additionally, Pacetti teaches the use of a mandrel for supporting and rotating a stent for the motivation of providing an apparatus for coating a stent to produce a useful medical device (Figure 1; column 4, lines 20-26; columns 1 and 2). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the claimed capability of working on a stent supported by wire because one of ordinary skill in the art would have been motivated to provide means for coating a stent in accordance with the teachings of Pacetti.

Regarding claim 8, Soldani teaches providing a quartz heating rod for drying the coating (column 6, lines 55-58), thus satisfying the claimed heating element. To the extent that the claimed heating element distinguishes over the quartz heating rod of Soldani, providing heating elements in coating apparatus for suitably drying coatings is well known. It would have been obvious to one of ordinary skill manner at the time of the invention to provide the claimed heating element because one of ordinary skill in the art would have been motivated to provide any known and suitable means for suitably drying the coatings, such as a well known heating element.

Soldani clearly teaches the limitation of claim 10 (column 3, lines 1-15).

Regarding claim 12, the claimed apparatus only requires the capability of using polymer and non-solvent mixtures. The apparatus of Soldani as modified by Pacetti is clearly capable of using such mixtures. To the extent that claim 12 positively requires the claimed mixtures, as noted above Soldani clearly teaches polymer and non-solvent mixtures.

8. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soldani in view of Pacetti, and further in view of Hays or Sobierski, and further in view of Thorn et al. as applied to claims 2, 5, 7, 8, 10-12, 22, 23, and 25-27 above, and further in view of Chouinard (US 6156064).

In order to provide a tubular medical device such as a stent with the ability to self expand, a stiffening element is required. Chouinard teaches means for inserting wound filaments to produce a tubular mesh in order to provide such a stiffening layer in a tubular medical device (Figures 1-6A; Abstract; column 2, lines 37-45; column 8, lines 10-20; column 9, lines 8-10 and lines 62-65; column 10, lines 31-42; column 11, lines 38-39). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the claimed means for insertion of filaments or a tubular mesh stiffening element because one of ordinary skill in the art would have been motivated to provide means for producing self expanding tubular medical devices in accordance with the teachings of Chouinard.

9. Claims 2, 5, 7, 8, 10-12, 22, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti in view of Soldani, and further in view of Hays or Sobierski, and further in view of Thorn et al.

The claims are rejected here in the alternative because they only require one spray means.

The rejection of claims 2, 5, 7, 8, 10-12, 22, 23, and 25-27 above is incorporated herein.

Pacetti is applied as above for teaching the claimed reserves, spray means, mixer means, and control unit. Pacetti also teaches the claimed cylindrical support element and nozzle spray means (Figure 1; column 4, lines 20-26). Pacetti does not teach the claimed first carriage, although Pacetti does teach providing relative motion between a support mandrel and nozzle. Soldani is applied as above for teaching the claimed first carriage as a suitable means of moving a nozzle. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide Pacetti with the claimed first carriage because one of ordinary skill in the art would have been motivated to use any suitable known means for providing the relative movement between nozzle and mandrel taught by Pacetti, such as the carriage means of Soldani.

Hays, Sobierski, and Thorn are applied as above. Soldani is applied as above for providing the claimed second carriage means and heating element.

10. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti in view of Soldani, and further in view of Hays or Sobierski, and further in view of Thorn et al. as applied to claims 2, 5, 7, 8, 10-12, 22, 25, and 26 above, and further in view of Chouinard.

Chouinard is applied as above in the rejection of claims 13-15.

Response to Arguments

11. Applicant's arguments with respect to claims 1 and 23 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael A. Tolin whose telephone number is 571-272-8633. The examiner can normally be reached on M-F 9am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Crispino can be reached on 571-272-1226. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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